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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,857	01/26/2004	Arthur Zaks	763510-3	9797

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EXAMINER	
HUYNH, CARLIC K	

ART UNIT	PAPER NUMBER
1612	

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02/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/764,857	ZAKS, ARTHUR	
	Examiner	Art Unit	
	CARLIC K. HUYNH	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' amendments and remarks filed on November 23, 2007 is acknowledged.

Status of the Claims

1. Claims 1-11 are pending in the application. Applicant has cancelled claim 2 in an "Amendment – After Non-Final Rejection" filed on November 23, 2007. Accordingly, claims 1 and 3-11 are being examined on the merits herein.

The objections to the Specification for use of trademarks and the objections to Claim 10 have been withdrawn in view of Applicants' amendments.

The rejections made under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 102(b) have been withdrawn in view of Applicants' amendments.

The following new grounds of rejections are necessitated by Applicants' amendments.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 4 and 5 recite the limitation "said imidazo[1,2-a]pyridine composition". Claims 4 and 5 are dependent on claim 1. It is noted that claim 1 recites a specific compound, "N,N,6-

trimethyl-2-p-tolyl-imidazo[1,2-a]pyridine-3-acetamide (zolpidem)" and not the generic "an imidazo[1,2-a]pyridine". Thus, there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-6, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) alone or in view of Holman (US 2002/0165246).

Meisler teaches treatment for women suffering from chronic fatigue syndrome, who oftentimes also struggle with chronic pain, comprising zolpidem and provigil (page 477 and 479-480). It is noted that zolpidem is well known in the art under the trademark AMBIEN® and has the chemical name of N,N,6-trimethyl-2-p-tolyl-imidazo[1,2-a]pyridine-3-acetamide L-(+)-tartrate.

Meisler does not explicitly teach oral or topical administration of provigil and zolpidem.

Holman teaches the oral and topical administration of zolpidem for sleep restoration (page 4, paragraph [0048]; and page 5, paragraph [0056]). Holman further teaches the therapeutic agent can also be used to treat pain (page 5, paragraph [0053]).

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compositions of zolpidem and provigil of Meisler to restore sleep because the composition of zolpidem of Holman are used for sleep restoration and according to Meisler, the sleep medication zolpidem is used to sufferers of chronic fatigue syndrome who also struggle with chronic pain.

The motivation to combine the compounds of Meisler to the compounds of Holman is that the compounds of Holman are used for sleep restoration. One of ordinary skill in the art would be motivated further to administer the composition of Meisler topically with a reasonable expectation of success because Holman teaches the administration of zolpidem topically.

Response to Arguments

4. Applicants' arguments, see "Remarks" filed on November 27, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 1, 3-6, and 9-11 has been fully considered and are persuasive. Claim 2 has been cancelled. Applicants argue that Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) teaches the occurrence of pain with chronic fatigue syndrome (CFS) but does not teach the use of zolpidem to treat pain, (only sleep problems). Moreover, Applicants argue that Holman (US 2002/0165246) teach the use of zolpidem as a sleep restorative agent. Applicants further argue that there is no motivation to combine the Meisler and Holman. These arguments are not persuasive.

Regarding Meisler, examiner maintains and argues that Meisler teach a method of treating chronic fatigue syndrome, whose patients oftentimes also suffer from pain, comprising administering provigil and zolpidem (pages 477 and 479-480). It is noted that Meisler does not

explicitly teach oral or topical administration of provigil and zolpidem. However, compositions are routinely made into various pharmaceutical dosage forms including oral and topical formulations. Thus it would be obvious the compositions of provigil and zolpidem can be administered either orally or topically.

Regarding Holman, Examiner points out Holman teach the use of zolpidem as a sleep restorative agent. However, the therapeutic agent used in Holman can also be used to treat pain (page 5, paragraph [0053]).

Although Holman is directed to sleep restoration, it clearly shows that topically application of zolpidem enters into the system. Therefore, one of ordinary skill in the art would expect zolpidem to have an effect against pain as well since it enters the system and the reference of Meisler shows the effectiveness of administered zolpidem and provigil to treat pain.

Thus, the Rejections under 35 U.S.C. § 103 to claims 1, 3-6, and 9-11 have been maintained.

5. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) alone or in view of Holman (US 2002/0165246) as applied to claims 1, 3-6, and 9-11 above, and in further view of Malin et al. (US 5,084,007).

It is noted that Kaplan et al. (US 4,501,745) and Kaplan et al. (US 4,382,938) are not used because the generic terminology of imidazo[1,2-a]pyridine has been removed in amended claim 1

Meisler does not teach pain caused by metastatic cancer.

Malin et al. teach derivatives of imidazo[1,2-a]pyridine can be used to treat chronic pain resulting from terminal cancer (column 3, line 53; and column 7, line 42). Since zolpidem is a specific imidazo[1,2-a]pyridine, it would be obvious to the skilled artisam that Malin et al. teach zolpidem.

It is noted that "terminal cancer" is well known in the art to be metastatic.

To a person of skill in the art at the time of the invention, it would have been obvious to employ the compositions of zolpidem and provigil of Meisler to treat pain resulting from metastatic cancer because the compounds of Malin et al. are imidazo[1,2-a]pyridine derivatives and according to Malin et al., imidazo[1,2-a]pyridine derivatives can be used to treat pain resulting from terminal cancer.

The motivation to combine the compounds of Meisler to the compounds of Malin et al. is that the compounds of Malin et al. are imidazo[1,2-a]pyridine derivatives and that such imidazo[1,2-a]pyridine derivatives treat pain resulting from terminal cancer.

Response to Arguments

6. Applicants' arguments, see "Amendment-After Non-Final Rejection" filed on November 27, 2007, with respect to "Rejections under 35 U.S.C. § 103" to claims 7 and 8 has been fully considered and are not persuasive. Claim 2 has been cancelled. Applicants have argued that Meisler (Journal of Women's Health & Gender-Based Medicine. 2000. Vol. 9, No. 5, pp. 477-482) does not teach zolpidem to treat pain. In response, Examiner states that Meisler is relevant for the reasons stated above. Thus, the Rejections under 35 U.S.C. § 103 to claims 7 and 8 are maintained.

Conclusion

7. No claims are allowable.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/
Primary Examiner, Art Unit 1612

ckh